PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference US040126WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IB2005/050537	International filing date *(day/month/year)* 11 February 2005 (11.02.2005)	Priority date *(day/month/year)* 27 February 2004 (27.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KONINKLIJKE PHILIPS ELECTRONICS, N.V.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 30 August 2006 (30.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Cecile Chatel e-mail: pt13@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2005/050537	11.02.2005	27.02.2004

International Patent Classification (IPC) or both national classification and IPC
G06F17/00, G06F19/00

Applicant
KONINKLIJKE PHILIPS ELECTRONICS, N.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Barba, M Telephone No. +49 89 2399-2732

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2005/050537

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-26
	No: Claims	
Inventive step (IS)	Yes: Claims	1-26
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following document:

D1: US-A-5 814 075 (KROLL ET AL) 29 September 1998 (1998-09-29)

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 The below mentioned lack of clarity notwithstanding (see Item VIII below) it appears that the subject matter of preset independent claim 1, when amended along the lines below indicated, would meet the requirements of novelty and inventive step as set out in Article 33(2) and (3) PCT, the reasons therefor being the following.

1.1 The present application relates to a method and apparatus for monitoring a heart condition, having small and portable dimensions, and that at the same time is both highly sensitive and highly specific and has low power consumption.
This feature is achieved by a multistage architecture, whereby a first stage having high sensitivity, but lower power consumption because implementing very simple analysis algorithm is coupled with a second stages processing data more throughly because implementing more complex analysis algorithms, therefore requesting higher power consumption, and wherein said second stages being activated by the first stage only in case of an alarm situation.
The architecture of the system of the present application achieves high sensitivity for alarm conditions with low power consumption and low computational throughput, and also achieves high specifity with more computational intensive algorithms which are only run whenever an alarm occurs.

1.2 Insofar as it can be understood in the light of the originally filed description, it appears that the subject matter of present independent claim 1 is directed to a heart condition monitoring apparatus comprising a first stage, second stages and memory means, wherein:

I) said memory means adapted to store computer program code means;

ii) first stage coupled to said memory means further comprising means adapted to receive data from a detected heart signal, means adapted to perform an analysis of said received signal in order to detect the occurring of a possible alarm condition, means adapted to activate said second stage;

iii) second stages comprising means to perform analysis of said received data in such a way to determine additional information regarding said sensed alarm conditions.

1.3 Moreover, it appears to this Authority that the system of present independent claim 1 should also be drafted in such a way to also comprise:

I) features related to means adapted to minimize the power consumption of said first stage and means to optimize sensitivity of said first stage to detect potential alarm conditions from the analysis of said sensed data;

ii) features related to meas adapted to maximize data throughput and analysis capability of the second stages activated by said first stage upon detection of said alarm conditions from said sensed data.

1.4 Document D1 discloses (see D1 column 3 lines 10 to 60; from column 4 line 50 to column 6 line 35; from column 7 line 3 to column 8 line 38; from column 11 line 10 to column 12 line 45; from column 12 line 65 to column 13 line 58) a system to control power for an implantable medical device having two power sources, a low power sources optimized for providing a continuous source of low power for cardiac monitoring, and a second power source being a high power source optimized for providing brief burst of high power for cardiac fibrillation when it is needed. Thus, in the system known from D1 the use of two different power sources is known, however it is used for the necessity of power burst for a defibrillator to be activated in case of a detected alarm condition; in the system of claim 1 the high power is used to enable a higher data throughput to run more complex analysis algorithm, in case of the occurring of an alarm situation.

1.5 The system of D1 has the problem that its power consumption in normal operation is not optimized; therefore, if one would need to increase the signal sensed analysis capability of the system of D1 in terms of higher data throughput, or more complex analysis algorithms to carried out, he has to implement solutions that would require

more power consumption in any operation condition.
This problem of D1 is solved by the system of claim 1, when amended along the lines above indicated, by providing a stage architecture, with first stage having a minimal power consumption and implementing simple signal analysis algorithm with the only purpose to implement a preliminary detection of an alarm condition, and a second stage implementing more complex signal analysis algorithms in order to perform a more detailed detection of the alarm condition, whereby said second stage is activated by the first stage only in case of occurrence of a possible alarm.

1.6 The solution to the problem of the prior art as proposed by claim 1 when amended along the lines above indicated, does not appear to be suggested or rendered obvious by system known from the prior art; therefore, the system of independent claim 1, when amended along the lines above indicated, meets the requirements of Article 33 (2) and (3) PCT.

2 The same reasoning also applies, mutatis mutandis, to the subject matter of remaining claims 2 to 26. Consequently it also appears that also the subject matter of claims 2 to 26, when amended along the lines above indicated, meets the requirements of Article 33 (2) and (3) PCT.

3 With regard to the assessment of the present claims 1 to 26 on the question whether they are industrially applicable, the following is stated.
Insofar as it is possible to be understood in the light of the originally filed description, it appears that the subject matter of present claims 1 to 26 relates to a method and apparatus for monitoring a heart condition, therefore it fulfills the requirements of industrial applicability as set out in Article 33 (4) PCT.

Re Item VII
Certain defects in the international application

3.1 At page 12, last paragraph, the description contains general statements that the

extent of protection may be expanded in some vague and not precisely defined way. Such general statements shall be deleted as contrary to Article 6 PCT, cf. also PCT Preliminary Examination Guidelines, C-III, 4.3a.

Re Item VIII
Certain observations on the international application

4 The application does not meet the requirements of Article 6 PCT, because claims 1, 7, 9 and 22 are not clear, the reasons therefor being the following.
Although claims 1, 7, 9 and 22 have been drafted as separate independent claims, they appear to relate effectively to the same subject matter and to differ from each other only with regard to the definition of the subject matter for which protection is sought and in respect of the terminology used for the features of that subject matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

With regard to the individual claims, the following comments are herein under submitted.

5 Present independent claim 1 does not meet the requirements of Article 6 PCT as to clarity, the reasons therefor being the following.

5.1 Some of the features in the apparatus claim 1 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

5.2 Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for

achieving this result.

5.3 The wordings "processor to be programmed", "optimum sensitivity", potential alarm conditions in the real time data", "to be optimized to minimize power consumption", "to activate the second set of programming instructions" and "to be optimized to maximize specifity" used in claim 1 are vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject matter of said claim unclear, Article 6 PCT.

5.4 Finally, it is clear from the description that the following features are essential to the definition of the invention:

I) features related to means adapted to minimize the power consumption of said first stage and means to optimize sensitivity of said first stage to detect potential alarm conditions from the analysis of said sensed data;

ii) features related to meas adapted to maximize data throughput and analysis capability of the second stages activated by said first stage upon detection of said alarm conditions from said sensed data.

Since independent claim 1 does not contain these features it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

6 The same objections as above are also valid, mutatis mutandis, for claims 2 to 26; consequently also claims 2 to 26 do not meet the requirements of clarity as set out in Article 6 PCT.

7 Moreover, claims 10, 13, 15, 16, 17 and 19 are also unclear for the following additional reasons.
The wordings "additional information includes a presence of one or more artifacts", "independent estimates", "a signal derived from a common mode current", "acceleration or patient impedance", "differentiating" and "technical aspects of a heart monitoring device" used in claims 10. 13, 15, 16, 17 and 19 respectively are vague

and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject matter of said claims unclear, Article 6 PCT.

8 Claims 25 and 26 are also unclear because despite the fact that they are method claims, include also features of an apparatus; therefore the category of said claims is not unambiguously defined and this fact creates in the reader a state of uncertainty when trying to assess the extent of the subject matter claimed, which is against the provisions of clarity as set out in Article 6 PCT.

To the European Patent Office

Entry into the European phase (EPO as designated or elected Office)

European application number	
PCT application number	PCT/IB2005/050537
PCT publication number	
Applicant's or representative's reference	PHUS040126EP1
1. Applicant Particulars of the applicant(s) are contained in the international publication or were recorded by the International Bureau subsequent to the international publication.	☑
Changes which have not yet been recorded by the International Bureau are set out here:	☐
Address for correspondence	
2. Representative 1 This is the representative who will be listed in the Register of European Patents and to whom notifications will be made	
Name	SCHOUTEN Marcus, M.
Address of place of business	P.O. Box 220 Eindhoven, 5600 AE Netherlands
Telephone	+31 40 2743505
Fax	+31 40 2743489
e-mail	
Any additional representative(s) is/are listed here:	☐
3. General Authorisation: An individual authorisation is attached.	☐
A general authorisation has been registered under No:	☐
A general authorisation has been filed, but not yet registered.	☐
The authorisation filed with the EPO as PCT receiving Office expressly includes the European phase.	☐
4. Request for examination Examination of the application under Art. 94 EPC is hereby requested. The examination fee is being (has been, will be) paid.	☑
Request for examination in an admissible non-EPO language:	☑ Verzocht wordt om onderzoek van de aanvrage als bedoeld in Art. 94.
5. Copies One or more additional sets of copies of the documents cited in the supplementary European search report are hereby requested.	☐
Number of additional sets of copies	
6. Documents intended for proceedings before the EPO 6.1 Proceedings before the EPO as designated Office (PCT I) are to be based on the following documents:	
the application documents published by the International Bureau (with all claims, description and drawings), where applicable with amended claims under Art. 19 PCT	☑

unless replaced by the amendments attached.	☐
Where necessary, clarifications should be attached as 'Other Documents'	
6.2 Proceedings before the EPO as elected Office (PCT II) are to be based on the following documents:	
the documents on which the international preliminary examination report is based, including any annexes	☐
unless replaced by the amendments attached.	☐
Where necessary, clarifications should be attached as 'Other Documents'	
If the EPO as International Preliminary Examining Authority has been supplied with test reports, these may be used as the basis of proceedings before the EPO.	☐
7. Translations	
Translations in one of the official languages of the EPO (English, French, German) are attached as crossed below:	☐
* In proceedings before the EPO as designated or elected Office (PCT I + II):	
Translation of the international application (description, claims, any text in the drawings) as originally filed, of the abstract as published and of any indication under Rule 13bis.3 and 13bis.4 PCT regarding biological material	☐
Translation of the priority application(s)	☐
It is hereby declared that the international application as originally filed is a complete translation of the previous application (Rule 38(5) EPC)	☐
* In addition, in proceedings before the EPO as designated Office (PCT I):	
Translation of amended claims and any statement under Art. 19 PCT, if the claims as amended are to form the basis for the proceedings before the EPO (see Section 6).	☐
* In addition, in proceedings before the EPO as elected office (PCT II):	
Translation of annexes to the international preliminary examination report	☐
8. Biological material	
The invention relates to and/or uses biological material deposited under Rule 28 EPC.	☐
The particulars referred to in Rule 28(1)(c) EPC (if not yet known, the depository institution and the identification reference(s)) [number, symbols, etc.] of the depositor) are given in the international publication or in the translation submitted under Section 7 on:	☐
page(s) / line(s)	
A copy of the receipt(s) of deposit issued by the depositary institution	
is attached	☐
will be filed at a later date	☐
A waiver of the right to an undertaking from the requester pursuant to Rule 28(3) EPC is attached.	☐
9. Nucleotide and amino acid sequences	
The items required under Rules 5.2 and 13ter PCT and Rule 111(3) EPC have already been furnished to the EPO.	☐
The sequence listing as part of the description is attached in PDF format.	☐
The sequence listing does not include matter that goes beyond the content of the application as filed.	☐
In addition, the sequence listing data is attached in computer-readable form in accordance with WIPO Standard 25.	☐
The sequence listing data in computer-readable form in accordance with WIPO Standard 25 is identical to the sequence listing in PDF format.	☐
10. Designation fees	
10.1 It is currently intended to pay seven times the amount of the designation fee. The designation fees for all the EPC contracting states designated in the international application are thereby deemed to have been paid (Art. 2 No. 3 RFees).	☑
AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LT LU MC	

NL PL PT RO SE SI SK TR

10.2 It is currently intended to pay fewer than seven designation fees for the following EPC contracting states designated in the international application: ☐

10.3 It is requested that no communication under Rules 85a(1) or 69(1) need be notified in respect of the contracting states not indicated. If an automatic debit order has been issued, the EPO is authorised, on expiry of the basic period under Article 79(2), to debit seven times the amount of the designation fee. If less than seven states are indicated, the EPO shall debit designation fees only for those states, unless it is instructed to do otherwise before expiry of the basic period. ☑

11. Extension of the European patent

This application is also considered as being a request for extension to all the non-contracting states to the EPC designated in the international application with which "extension agreements" were in force on the date of filing the international application. However, the extension only takes effect if the prescribed extension fee is paid. ☑

It is currently intended to pay the extension fee for the following states:

12. List of enclosed documents

	Description of document	Original file name	Assigned file name

13. Automatic debit order ☑

Currency: EUR

The European Patent Office is hereby authorised, under the Arrangements for the automatic debiting procedure, to debit from the deposit account any fees and costs falling due.

Deposit account number: 28090021

Account holder: Philips International B.V.- IP&S

14. Reimbursements (if any) should be made to the following EPO deposit account: ☑

Number and account holder: Philips International B.V.- IP&S, 28090021

15. Fees

		Factor/Reduction applied	Fee schedule	Amount to be paid
15-1	002e Fee for supplementary European search for applications filed before 01.07.2005	0	720.00	0.00
15-2	005 Designation fee	7	80.00	560.00
15-3	006e Examination fee (Euro-PCT without supplementary European search report)	0.8	1 490.00	1 192.00
15-4	015 Claims fee	16	45.00	720.00
15-5	020 Basic national fee for an international application	1	95.00	95.00
15-6	033 Renewal fee for the 3rd year	1	400.00	400.00
	Total:		EUR	2 967.00

16. Annotations

17. Signature(s) of applicant(s) or representative

Place: Eindhoven

Date: 06.June 2006

Signed by: NL, Philips IP&S, J. van der Veer 1086

Capacity: (Representative)